## 1. ABSTRACT


- **Title:** A longitudinal study of 4 cohorts of patients with psoriasis and psoriatic arthritis: one treated with Otezla® (apremilast), one with an injectable comparator drug, one with an oral comparator drug and one with an oral and an injectable comparator drug

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- **Keywords:** Apremilast, psoriasis, psoriatic arthritis, adverse events, drug safety
- **Rationale and Background :** Otezla (apremilast) is a newly marketed drug to treat psoriasis and psoriatic arthritis (PSA). Real world safety data of Otezla is limited.
- **Research Question and Objectives:** To compare the rates of adverse events of special interest (AESI) among patients using Otezla compared with patients using other psoriasis or PsA treatments. AESI were selected based on those observed in the clinical trials of Otezla, Otezla's mechanism of action, nonclinical data, possible class effects, known comorbidities in patients with psoriasis or PSA, and safety issues identified in similar products.
- **Study Design:** Cohort study
- **Setting:** UK general practice
- **Subjects and Study Size, Including Dropouts:** 782 Otezla users and 3 matched cohorts: oral treatments only, injectable treatments only and oral+injectable treatments
- **Variables and Data Sources:** Prescription codes for psoriasis and PSA treatments and diagnosis codes for malignancy, opportunistic and serious infections, suicide and suicidal ideation, treated depression, major adverse cardiac events (MACE), vasculitis, tachyarrhythmia, hypersensitivity, mortality, and treated anxiety as recorded in the United Kingdom Clinical Practice Research Datalink (CPRD) GOLD and Aurum, electronic health record databases captured by general practioners via two distinct patient management software packages.
- **Results:** In this population of 782 Otezla users and 15,454 matched comparison drug users followed for between 0 and 59 months, there were no incident Otezla-exposed cases of vasculitis, hematologic cancer, treated depression, or suicidal behaviors. Rates of mortality, MACE, tachyarrhythmia, solid cancers, non-melanoma skin cancers, treated anxiety and hypersensitivity were similar between the Otezla exposed cohort and the comparison cohorts. In CPRD GOLD, the rate of opportunistic and serious infections was similar between the Otezla cohort, the oral treatment only cohort and the oral+injectable cohort but was lower in the injectable treatment only cohort. Infection rates were similar in all 4 cohorts in the CPRD Aurum study.
- **Discussion:** The numbers of AESIs in all cohorts were low and there was no excess of any AESI associated with Otezla use.
- **Marketing Authorization Holder(s)** Amgen Europe B.V.

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